MAY 21 2001

K010936

7.0 Premarket Notification 510(k) Summary

Submitter

W.L. Gore and Associates, Inc.
3450 W. Kiltie Lane
Flagstaff, AZ 86002

Date Prepared: March 26, 2001

Contact: R. Larry Pratt

Applicant Device

SEAMGUARD® Staple Line Reinforcement Material in pledget configuration.

Applicant Device Indication For Use

The device is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using linear surgical staplers.

The device is indicated for use in the buttressing and reinforcing of staple lines during lung resections (e.g., wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections, segmentectomies, pneumonectomies, pneumoreduction, pneumectomies) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repairs, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The device can be used with anastomotic staplers or with non-anastomotic staplers.

Predicate Device

The currently marketed SEAMGUARD® Staple Line Reinforcement Material in sleeve configuration is cited as a predicate device which has been found to be substantially equivalent through the premarket notification process.

Technological Characteristics

The applicant device has the same intended use and the same indications as the predicate SEAMGUARD® Staple Line Reinforcement Material.

The applicant device is composed of the same inert ePTFE material as the predicate device, laminated to a layer of an amorphous fluoropolymer material. The amorphous fluoropolymer material is substantially equivalent to the material used in other GORE® products previously cleared for use in cardiovascular and neurological procedures. Biocompatibility test and animal study data reveal that the applicant device possesses the requisite characteristics to function safely in its intended use. The mechanical strength data and performance data indicate that the applicant device has the necessary biological, structural and mechanical characteristics required for the effective buttressing and reinforcing of staple lines. The technical, biocompatibility, descriptive and performance data presented demonstrate that the applicant device is substantially equivalent to its cited predicate device and that it is safe and effective for its intended use.

Safety and Effectiveness Conclusions

The applicant SEAMGUARD® Staple Line Reinforcement Material is substantially equivalent to the predicate SEAMGUARD® Staple Line Reinforcement Material with regard to intended use and indications. Both devices fulfill their equivalent clinical functions by buttressing and reinforcing staple lines.

The applicant device is substantially equivalent to the predicate SEAMGUARD® Staple Line Reinforcement Material with regard to device manufacturing, blood and tissue compatibility, packaging, mechanical strength, quality characteristics, and sterilization processes.

The descriptive information and performance data contained within this Premarket Notification submission are sufficient to demonstrate substantial equivalence of the applicant device to the predicate device. There are no patient safety concerns raised as a result of the clearance of the applicant device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Mr. R. Larry Pratt
Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 West Kiltie Lane
P.O. Box 500
Flagstaff, Arizona 86002

Re: K010936
Trade/Device Name: SEAMGUARD™ Staple Line Reinforcement Material
Regulation Number: 878.3300
Regulatory Class: II
Product Code: FTL
Dated: March 26, 2001
Received: March 28, 2001

Dear Mr. Pratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010936

Device Name: SEAMGUARD® Staple Line Reinforcement Material

Indications For Use:

SEAMGUARD® Staple Line Reinforcement Material is intended for use as a prosthesis for surgical repair of soft tissue deficiencies using linear surgical staplers. The device is indicated for use in the buttressing and reinforcing of staple lines during lung resections (e.g., wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections, segmentectomies, pneumonectomies, pneumoreduction, pneumectomies) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repairs, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). The device can be used with anastomotic staplers or with non-anastomotic staplers.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010936

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)